REMARKS

Applicants and their undersigned representative respectfully acknowledge the time and courtesy extended them by the Examiners, Mr. Betton and Mr. Marschel, during the Interview conducted May 31, 2007. The following Remarks serve as a summary of the interview by applicants.

The Amendments

The claims are amended to address the 35 U.S.C. §112 issues and clarify the nature of the active substance by incorporating dependent claim limitations, fully supported by the disclosure, into claim 1. The amendments were discussed with the Examiners during the Interview. It is believed the amendments render moot the existing rejections for the reasons discussed below. Support for new claims 61-63 is found in the specification at page 4, lines 3-5, and in the Examples at pages 9-18.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Restriction Requirement

Pursuant to the above amendments, it is believed that the current claims are directed only to the elected subject matter.

The Rejection under 35 U.S.C. §112, first paragraph

It is believed that the above amendments to the claims render moot the rejection of claims 33 and 47 under 35 U.S.C. §112, first paragraph. The "eliminate" and "prevent" terms forming the basis for the rejection are no longer in the claims.

The Rejection under 35 U.S.C. §102

The rejection of claim 33 under 35 U.S.C. §102, as being anticipated by Goldenberg (WO 98/46211) is respectfully traversed.

It is believed that the rejection is overcome by the above amendment to claim 33. Previous claim 35 was not subject to the rejection under 35 U.S.C. §102 and part of the substance of claim 35 is now incorporated into the independent claim 33. Thus, claim 33 now recites that the active substance "is a small molecule drug which is: a drug that kills fat

cells; methotrexate; bromo-deoxyuridine; actinomycin D; nocodazole; brefeldin A; a beta-adrenergic stimulator; or, an alpha-2 adrenergic inhibitor."

Goldenberg discloses sustained release formulations of alginate beads with a biologically active agent. As the biologically active agent, Goldenberg discloses proteins; see, e.g., page 10, lines 6-9, and pages 10-12 as a whole. Goldenberg provides no disclosure of a composition or method using "a small molecule drug which is: a drug that kills fat cells; methotrexate; bromo-deoxyuridine; actinomycin D; nocodazole; brefeldin A; a beta-adrenergic stimulator; or, an alpha-2 adrenergic inhibitor." For this reason, at least, Goldenberg fails to anticipate the claimed invention.

Further, while Goldenberg provides a broad generic recitation of administration methods for its formulations at page 12, line 27, to page 13, line 3, there is no specific disclosure or direction to an embodiment of administering "by injection into the adipose tissue at a local area such that undesired adipose tissue in the local area is selectively reduced." The only method examples of Goldenberg pertain to a systemic administration having a systemic effect. See, e.g., page 22 pertaining to an animal model wherein a general systemic weight loss is achieved. There is no disclosure or suggestion from Goldenberg that elimination or reduction in tissue occurs in the local area of the injection exclusively or to a significantly higher degree than other areas of the body not subject to the injection, i.e., there is nothing to suggest an effect "selectively" at the local area of administration. Goldenberg provides no teaching or suggestion of a selective local administration or a selective local effect. For this additional reason, Goldenberg fails to anticipate the claimed invention.

For the above reasons, at least, the rejection of claim 33 under 35 U.S.C. §102 over Goldenberg should be withdrawn.

The Rejections under 35 U.S.C. §103

The several rejections of the claim 33 under 35 U.S.C. §103, as being obvious over Goldenberg, alone, or in view of the Hutchinson, Ogawa or Johnson articles, or in view of Silvestri (U.S. Patent No. 5,126,147), or in view of Silvestri further in view of the Merwin article, are respectfully traversed.

Initially, it is believed that the rejection is overcome by the above amendment to claim 33. Previous claim 35 was not subject to these rejections under 35 U.S.C. §103 and part of the substance of claim 35 is now incorporated into the independent claim 33. Thus, claim 33 now recites that the active substance "is a small molecule drug which is: a drug that

kills fat cells; methotrexate; bromo-deoxyuridine; actinomycin D; nocodazole; brefeldin A; a beta-adrenergic stimulator; or, an alpha-2 adrenergic inhibitor." As pointed out above, Goldenberg's teachings relate to the use of proteins as the active agent and give no teaching or suggestion of the small molecule drugs used according to the claimed methods.

The secondary references also provide no teaching or suggestion of the small molecule drugs used according to the claimed methods. Hutchinson relates to administration of polypeptides, not small molecules. Ogawa relates to a formulation for the release of leuprolide acetate used for the treatment of prostate cancer. Ogawa provides no teachings or suggestion regarding a method for reducing adipose tissue using a small molecule drug which is: a drug that kills fat cells; methotrexate; bromo-deoxyuridine; actinomycin D; nocodazole; brefeldin A; a beta-adrenergic stimulator; or, an alpha-2 adrenergic inhibitor. Johnson relates to a formulation for sustained release of human growth hormone. The hormone is not a small molecule and Johnson provides no teachings or suggestion regarding a method for reducing adipose tissue using a small molecule drug which is: a drug that kills fat cells; methotrexate; bromo-deoxyuridine; actinomycin D; nocodazole; brefeldin A; a beta-adrenergic stimulator; or, an alpha-2 adrenergic inhibitor. Silvestri relates to a formulation for sustained release of a "macromolecular bioactive agent of biological origin." It provides no teachings regarding small molecules, particularly those of the instant claims. Merwin relates to chimeric fibroblast growth factors. It also provides no teachings regarding small molecules, particularly those of the instant claims. Thus, it should be evident that none of the cited secondary references provide any suggestion to modify Goldenberg to use a small molecule drug which is: a drug that kills fat cells; methotrexate; bromo-deoxyuridine; actinomycin D; nocodazole; brefeldin A; a beta-adrenergic stimulator; or, an alpha-2 adrenergic inhibitor.

For the above reasons, at least, the rejections of claim 33 under 35 U.S.C. §103 should be withdrawn.

However, applicants additionally urge that, even if prior art exists which suggests the use of small molecule drugs (such as: a drug that kills fat cells; methotrexate; bromo-deoxyuridine; actinomycin D; nocodazole; brefeldin A; a beta-adrenergic stimulator; or, an alpha-2 adrenergic inhibitor) for reducing adipose tissue, one of ordinary skill in the art would not be motivated to modify the Goldenberg method in view of such teachings to arrive at the claimed invention.

First of all, Goldenberg is specific to the use of specific alginate gel bead materials for achieving sustained release of proteins. The Background portion of Goldenberg makes clear

that the invention is directed to a find a material that is specific to solving the problem of sustained release that was specific to proteins. There is no suggestion from Goldenberg – and no reasonable expectation of success – that their alginate gel beads, specifically designed for use with proteins, would be useful for sustained release of small molecule drugs, such as those used in the claimed invention.

Further, Goldenberg and the secondary references also fail to disclose the specific manner of local administration and selective local effect of the claimed invention, i.e., administration by "injection into adipose tissue at a local area such that undesired adipose tissue in the local area is selectively reduced." Goldenberg provides no teachings which give any hint to one of ordinary skill in the art that a controlled release formulation could be injected into adipose tissue at a local area to reduce the adipose tissue selectively in that local area. To the contrary, all the teachings in Goldenberg relate to administration of a sustained-release formulation to achieve general/systemic effects on the patient, for example, overall weight loss. Similarly, all of the secondary references also relate only to systemic delivery of drugs to achieve a general effect. There is no suggestion in any of the references that a specific local area of adipose tissue could be targeted by injection directly into the adipose tissue and that selective reduction of the adipose tissue in that local area could be achieved, as opposed to a systemic effect. A general weight loss effect taught by the art suggests to one of ordinary skill in the art that the weight loss is relatively evenly distributed in the patient and, thus, is not suggestive of the reduction of adipose tissue targeted to the local area of injection.

Applicants' disclosure gives ample guidance as to the meaning of the "local area" and the "selective" effect thereon which is consistent with the art-recognized meaning. The specification distinguishes the inventive local administration with selective effect from general administration with systemic effect in the Background section of the specification. Also in the Background, it points out other art which utilizes local administration methods for different effects. Thus, it is clear that local administration and selective effect are terms used in the art having a defined meaning. Further, the specification gives representative examples of specific types of administration to achieve the local area selective effect (see, e.g., page 6, third full paragraph, and paragraph bridging pages 6-7). Finally, the specification provides in vivo and in vitro examples with rat models demonstrating specific applications of the method and showing their selective localized effect (see pages 8-18 of the specification).

Additionally, Goldenberg and the secondary references provide no specific disclosure of any method involving administration of a substance particularly by "injection into the

adipose tissue." Goldenberg provides a laundry list of generic administration methods at pages 12-13. These include "subcutaneous" and "injectable" among others. But there is no indication in Goldenberg and the secondary references of a desire to achieve anything other than a systemic effect. Thus, the general administration methods listed would only have been considered by one of ordinary skill in the art to the extent that they provide a systemic effect. As discussed at the Interview, it is true that a subcutaneous injection could be used – depending on the area of administration and the manipulation of the manner of injection – to achieve injection into adipose tissue. However, it is also true that not all subcutaneous injections result in an injection into adipose tissue. Since Goldenberg and the secondary references provide no suggestion of any desirability of a selective local administration and selective local effect – to the contrary they desire a systemic effect – one of ordinary skill in the art would not have been motivated from these teachings to manipulate a subcutaneous injection in a way which results in injection into adipose tissue. All of the Goldenberg examples involve subcutaneous administration, i.e., under the skin, but provide no disclosure or suggestion of injection into adipose tissue or any local effect. To the contrary, they suggest only a systemic effect. These methods of Goldenberg also would not inherently result in the claimed invention. There is no evidence that all subcutaneous injections result in injection into adipose tissue. Inherency in the patent law requires that the non-disclosed element "necessarily and inevitably" occurs, as opposed to possibly occurring; see, e.g., In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); and In re Oelrich, 212 USPQ 323, 326 (CCPA 1981). There is no evidence on the record that subcutaneous administration necessarily and inevitably results in injection into adipose tissue. Thus, it is urged that the claimed invention is further distinguished from the cited prior art by the "injection into the adipose tissue" recitation.

For the above reasons, it is urged that no combination of the cited prior art renders the claimed invention obvious to one of ordinary skill in the art. Thus, these rejections under 35 U.S.C. §103 should be withdrawn.

The Rejection under 35 U.S.C. §103 based primarily on Richardson

The rejection of claims 35, 36, 38 and 51-60 under 35 U.S.C. §103, as being obvious over Richardson (U.S. Pub. No. 2003/0022856) in view of Greenway (U.S. Patent No. 4,525,359) and Greenway (U.S. Patent No. 4,588,724), is respectfully traversed.

Richardson is not prior art. In fact, the Richardson publication is the publication of

this very application. The publication is not prior art to applicants and applicants' own application cannot be used as a basis for rejection. Thus, the rejection requiring Richardson must be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

No fee, other than the 2-Month Extension of Time being paid herewith, is believed to be due with this Amendment. However, the Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/John A. Sopp/
John A. Sopp
Registration No. 33,103
Attorney for Applicants

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1
2200 Clarendon Blvd. Suite 1400
Arlington, Virginia 22201
Telephone: (703)243-6333
Facsimile: (703) 243-6410

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